



U.S. Food and Drug Administration

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## FDA's Role in Animal Health Yes! No! Maybe So! – What FDA Does and Does Not Regulate



By Ashley Steel, Center for Veterinary Medicine, FDA

Each week, FDA's Center for Veterinary Medicine (CVM) receives a variety of phone calls and e-mails from consumers asking questions like, "Who regulates flea and tick products?" and "How do I treat my cat's urinary tract infection?" While CVM's Communications Staff is happy to direct consumers to the appropriate resources, it may be helpful to know that FDA is not the only organization responsible for protecting animal health. FDA regulates the drugs, devices, and feed given to or used on over one hundred million companion and food-producing animals in the U.S. Several other government and non-government organizations also play a role in animal health.

### Yes!

**Animal Drugs** – The Federal Food, Drug, and Cosmetic Act gives FDA the legal authority to approve and regulate drugs for animals. Before a drug company can market an animal drug, the company must get the drug approved by FDA. To get FDA approval, the drug company must prove that:

For the complete definition of the term "drug," please see the Federal Food, Drug, and Cosmetic Act at [Section 201\(g\) \[21 U.S.C. 321\]](#).

- The drug is safe and effective for a specific use in a specific animal species. If the drug is for use in food-producing animals, the drug company must also prove that food products made from treated animals are safe for people to eat;

- The manufacturing process is adequate to preserve the drug's identity, strength, quality, and purity. The drug company must show that the drug can be consistently produced from batch to batch; and
- The labeling is appropriate and truthful. The drug company must make sure that the labeling contains all necessary information to use the drug safely and effectively, including the risks associated with the drug.

FDA's role does not stop after an animal drug is approved. As long as the animal drug is marketed in the U.S., FDA continues to monitor:

- The drug's safety and effectiveness;
- The drug's manufacturing process to make sure quality and consistency are maintained from batch to batch; and
- How the drug is marketed to make sure the advertisements are truthful and not misleading.

Besides the standard approval process, two additional pathways to the marketplace are available for some animal drugs for minor species or minor uses in a major species. These two pathways are conditional approval and indexing.

For more information about the animal drug approval process, please visit:  
<http://www.fda.gov/AnimalVeterinary/ResourcesforYou/AnimalHealthLiteracy/ucm219207.htm>

<http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/NewAnimalDrugApplications/default.htm>

For an online database of FDA-approved animal drugs, please see Animal Drugs @ FDA:  
<http://www.accessdata.fda.gov/scripts/animaldrugsatfda/>

For more information about minor species, minor uses, conditional approval, and indexing, please visit:  
<http://www.fda.gov/AnimalVeterinary/ResourcesforYou/AnimalHealthLiteracy/ucm189540.htm>

<http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/MinorUseMinorSpecies/default.htm>

<http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/MinorUseMinorSpecies/ucm070206.htm>



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**Animal Devices** – The key difference between an animal device and an animal drug is how the product works. If it relies on a chemical action occurring in or on the animal's body to work, the product is a drug, not a device. If it needs to be metabolized by the animal's body to work, the product is a drug, not a device.

For the complete definition of the term "device," please see the Federal Food, Drug, and Cosmetic Act at [Section 201\(h\) \[21 U.S.C. 321\]](#).

Antibiotics, anesthetics, and insulin are examples of drugs. Needles, syringes, surgical instruments, X-ray equipment, certain diagnostic test kits, and dental appliances are examples of devices.

For more information about animal devices, please visit: <http://www.fda.gov/AnimalVeterinary/ResourcesforYou/>

Unlike animal drugs, animal devices do not have to be approved by FDA before they can be marketed. Manufacturers and distributors of animal devices are responsible for making sure they are safe, effective, and properly labeled. FDA has the authority to take regulatory action if an animal device is adulterated or misbranded.

**Animal Feed** – The Federal Food, Drug, and Cosmetic Act requires food for both people and animals to be:

- Safe;
- Produced under sanitary conditions; and
- Truthfully labeled.

Animal feed includes pet food and pet treats, as well as feed for food-producing animals, such as

cattle, pigs, chickens, and farmed-raised fish. Unlike animal drugs, animal feed does not have to be approved by FDA before it can be marketed. However, FDA makes sure the ingredients in the feed are safe and have an appropriate function, and many ingredients must be approved by FDA before they can be used in animal feed. FDA also evaluates the human food safety aspect of animal feed for food-producing animals. That is, FDA makes sure it's safe for people to eat food products made from animals that ate the feed.

For more information about animal feed, please visit: <http://www.fda.gov/AnimalVeterinary/Products/AnimalFoodFeeds/default.htm>

**Turtles Under 4 Inches** – Under federal law, FDA banned the sale of turtles less than 4 inches long in 1975 because of human health concerns. Small turtles may seem like fun additions to the home, but they carry dangerous bacteria called *Salmonella*.

For more information about turtle safety, please visit: <http://www.fda.gov/downloads/AnimalVeterinary/ResourcesforYou/AnimalHealthLiteracy/UCM117790.pdf>

**No!**

**Vaccines for Animal Diseases** – FDA does not regulate vaccines for animal diseases. Veterinary biologics, including vaccines for animal diseases, are regulated by the U.S. Department of Agriculture.

For more information about vaccines for animal disease, please visit: [http://www.aphis.usda.gov/animal\\_health/vet\\_biologics/](http://www.aphis.usda.gov/animal_health/vet_biologics/)

**Maybe So!**

**Pharmacies** – Pharmacists are licensed by their state board of pharmacy and must follow the rules and



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regulations of that state board. FDA is responsible for approving and regulating the drugs sold in pharmacies. Some pharmacies also compound drugs. FDA has rules and policies about compounding drugs that apply to those pharmacies.

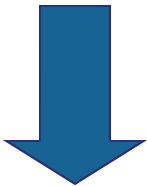
For more information about boards of pharmacy and for contact information for each state board of pharmacy, please visit the website of the National Association of Boards of Pharmacy (NABP) at <http://www.nabp.net/>.

For more information about the compounding of animal drugs, please visit:

<http://www.fda.gov/AnimalVeterinary/ResourcesforYou/FDAandtheVeterinarian/ucm077389.htm>

Please refer questions about a specific drug for your animal or drug pricing to your veterinarian or pharmacist.

**Practice of Veterinary Medicine** – Veterinarians are licensed by their state veterinary licensing board and must meet the requirements of the licensing board to practice in that state. FDA regulates the devices and drugs that veterinarians use, and the conditions under which veterinarians may prescribe drugs for extra-label uses.



### What does “extra-label” mean?

When an approved drug is used in a manner other than what is stated on the label, it is an extra-label use. This is commonly called an “off-label” use because the drug is used in a way that is “off the label.”

**Flea and Tick Products** – FDA regulates some flea and tick products for animals while the Environmental Protection Agency (EPA) regulates others. If a product is regulated by EPA, it will have an EPA Registration Number (sometimes written as “EPA Reg. No.”) on the label. If a product is regulated by FDA, it will typically have the statement “Approved by FDA” followed by a six-digit New Animal Drug Application (NADA) or Abbreviated New Animal Drug Application (ANADA) number on the label.

For more information about flea and tick products, please visit:

<http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm169831.htm>

<http://www.epa.gov/pesticides/health/pets.htm>



For more information about veterinary licensing boards and for contact information for each state veterinary licensing board, please visit the website of the American Association of Veterinary State Boards (AAVSB) at <http://www.aavsb.org/>.

For more information about extra-label drug use in animals, please visit:

<http://www.fda.gov/AnimalVeterinary/ResourcesforYou/FDAandtheVeterinarian/ucm077390.htm>

<http://www.fda.gov/AnimalVeterinary/NewsEvents/FDAVeterinarianNewsletter/ucm100268.htm>

Please refer specific questions about your animal’s health to your veterinarian.



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**Milk, Eggs, Meat, Poultry, and Catfish** – The responsibility of food safety is shared by FDA and the U.S. Department of Agriculture (USDA). FDA regulates milk and milk products, such as cheese, cream, and ice cream. FDA also regulates “shell eggs” which, as the name implies, are eggs still inside their shells. USDA regulates “egg products” which are eggs that have been removed from their shells for processing. In general, USDA regulates meat, poultry, and catfish.



For more information about food and food safety, please visit:

<http://www.fda.gov/Food/default.htm>

[http://www.fsis.usda.gov/Food\\_Safety\\_Education/usda\\_meat\\_&\\_poultry\\_hotline/index.asp](http://www.fsis.usda.gov/Food_Safety_Education/usda_meat_&_poultry_hotline/index.asp)

[http://www.fsis.usda.gov/About\\_FSIS/OCIP/index.asp](http://www.fsis.usda.gov/About_FSIS/OCIP/index.asp)

[http://www.usda.gov/wps/portal/usda!/ut/p/c4/04\\_SB8K8xLLM9MSSzPy8xBz9CP0os\\_gAC9-wMJ8QY0MDpxBDA09nXw9DFxcXQAA\\_2CbEdFAEUojoE!/?navtype=SU&navid=FOOD\\_NUTRITION](http://www.usda.gov/wps/portal/usda!/ut/p/c4/04_SB8K8xLLM9MSSzPy8xBz9CP0os_gAC9-wMJ8QY0MDpxBDA09nXw9DFxcXQAA_2CbEdFAEUojoE!/?navtype=SU&navid=FOOD_NUTRITION)

<http://www.foodsafety.gov/>

### Not on the Regulatory Radar

Some products on the market for animals don't fall under the regulatory authority of any government or non-government organization, including:

- Cat litter
- Pet accessories, such as toys, bed, and crates
- Grooming aids

For questions or concerns about FDA-regulated animal products, contact CVM's Communications Staff at:

Phone: 240-276-9300

Fax: 240-276-9115

E-mail: [AskCVM@fda.hhs.gov](mailto:AskCVM@fda.hhs.gov)

Address: 7519 Standish Place, Rockville, MD 20855